

# Rexall®

JUN 24 '03 JUN 24 A6:33

JUN 17 2003

June 13, 2003

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given that Rexall, Inc. ("Rexall") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Rexall brand name bearing the following statement(s) on the label and/or in the labeling:

Menopause Vitamins To Go®: [It] promotes vitality. [It] is a balanced combination formulated to promote vitality and naturally support your body as your nutritional requirements change when you enter this phase of your life. [It] provides relief from symptoms associated with menopause, such as relief from hot flashes and night sweats. Each Rexall Menopause Vitamins To Go packet contains:

Adult Multivitamin: A complete, balanced, one-per-day multiple vitamin and mineral formula designed to meet the nutritional concerns of menopausal women.

Calcium 600 mg: Helps build and maintain good bone health and is essential for healthy teeth, blood, muscles and cardiovascular function.

Natural Vitamin E 200 IU:...helps maintain cardiovascular and circulatory function and is found in a base of natural olive oil and olive juice extract, with powerful antioxidant properties.

Evening Primrose Oil: A source of gamma-linolenic acid (GLA), an essential omega-6 fatty acid that helps maintain hormonal balance and healthy-looking skin and is essential for healthy joints.

975 0162

LET

12171

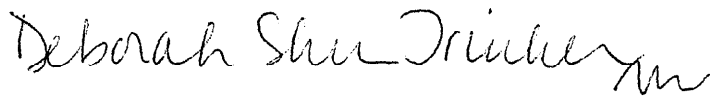
6111 Broken Sound Parkway, N.W. · Boca Raton · Florida · 33487-3613  
Tel 561-241-9400 Fax 561-995-5188

Food and Drug Administration  
June 13, 2003  
Page 2

Standard Black Cohosh 340 mg: Naturally supports healthy changes associated with menopause and provides relief for menopausal symptoms, such as hot flashes and night sweats.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Cordially,

A handwritten signature in cursive script that reads "Deborah Shur Trinker".

Deborah Shur Trinker, Esq.  
Senior Vice President  
Regulatory Affairs

Enclosures